K961120

MAY 10 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Administrative Information

1.1 Submitter

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1.3 Date Prepared

March 18, 1996

2.0 Device Identification

2.1 Trade/Proprietary Name

Ost-Reg Marker System for Stereotaxic Navigation

2.2 Common Name

Marker System for Stereotaxic Navigation

2.3 Classification

Stereotaxic Instrument

Classification Number	Class	Regulation Number
84HAW	II	882.4560

3.0 Predicate Device Identification

	STP Complete Module Set	Wurzburg Titanium Bone Screws
510(k) Number	K892425	K854886
Classification Name	Stereotaxic Instrument	Bone Screw
Classification Number	84HAW	87HWC
Class	II	II
Regulation Number	882.4560	888.3040

4.0 Product Description

4.1 Background

Stereotaxy refers to a group of neurosurgical procedures involving the establishment of a three-dimensional coordinate system where any anatomical point can be determined as a set of coordinates (x,y,z). These procedures are used for resections, generating lesions, biopsy, implantation of radioisotopes, and small field external beam radiotherapy. Stereotactic systems all involve the same basic operating principle; by establishing known reference points and maintaining a fixed position between these points and the patient's anatomy throughout imaging, surgery, and/or radiotherapy, minimally invasive procedures can be conducted. Reference points are created using fiducial markers visible both during imaging (CT, MRI, angiography, etc.) and surgery or radiotherapy. Stereotaxic localization uses these points to assemble images into three-dimensional space with known coordinates at every position, facilitating surgical or treatment planning.

Fiducial markers have traditionally been incorporated into a stereotactic frame fixed to the patient's head with percutaneous pins before imaging and left in place for the duration of surgery or treatment. Several drawbacks are associated with this method. Patient comfort is compromised by the fixation pins and the resulting immobilization. The frames are often cumbersome for the physician to work around, limiting visibility and approach angles. Depending upon the material used, interactions between the frame and magnetic fields for imaging may occur, reducing system accuracy. Finally, access to the caudal two-thirds of the brain is limited with some stereotactic frames. As a result, skull base tumors often necessitate highly-invasive surgery and general

anesthetic. These factors have spurred interest in establishing stereotactic reference points without a frame.

4.2 Design

Rather than using fiducial markers external to the patient--consequently requiring the patient to be immobilized in a frame--the Marker System for Stereotaxic Navigation creates reference points fixed to the patient's skull. The system uses bone screws, adapted from craniofacial fracture fixation, to secure three to five markers into the calvarium. Each assembly consists of a screw, base component, and marker ball or optical marker. Screws are made from commercially pure titanium, have threaded lengths of 6 mm, and come in two overall lengths--9 mm and 18 mm--to accommodate different soft tissue thicknesses. A polysulfone base component screws onto the head of each screw and holds a transparent marker ball of the same material or an aluminum alloy optical marker. The marker ball, containing the medium visible during imaging, is 5 mm in diameter and has an internal cavity 2 mm in diameter. For angiography or CT imaging, these markers contain a gold ball for contrast. Markers intended for MRI and PET use are hollow, allowing injection of appropriate contrast media such as gadolinium, copper sulfate, or ^{18}F-labeled fluorodeoxyglucose solutions[1]. This cavity is accessed by a hole 0.6 mm in diameter descending from the top of the marker. Flat optical markers sit in the base component with the same profile as the marker balls. Fabricated from an aluminum alloy, they are anodized black and have a machined spot in the center where the true silver color of the alloy is visible; the position of this spot is identical to the center of the imaging marker ball. See Exhibit F for engineering drawings.

4.3 Biocompatibility

Marker System bone screws are made from commercially pure titanium, noted for its high biocompatibility, corrosion resistance, lack of toxicity, and minimal artifact in CT and MRI scans. Several of these features are due to the oxide layer spontaneously formed on the titanium surface from exposure to oxygen and strongly bonded to the underlying metal. Titanium also allows for excellent osseointegration, creating very stable screw fixation due to the lack of connective tissue between the screw and

[1] Mark Levivier, M.D., et. al., "Diagnostic yield of stereotactic brain biopsy guided by positron emission tomography with [18F]fluorodeoxyglucose," *Journal of Neurosurgery*, 82(3): 445-452, March 1995.

bone[2]. The base components and imaging markers are made from polysulfone complying with FDA regulation 177.1655. Other components supplied with the system--gold balls within CT/angiography imaging markers and aluminum alloy optical markers--are not implanted or skin-contacting. Additional material information can be found in Exhibit E.

4.4 Application

Each marker is placed by first making a small stab incision and then drilling a pilot hole for the bone screw with a twist drill. Skull thickness must be determined before drilling to prevent the pilot hole from extending into the dura. Proper screw length--9 mm or 18 mm--is selected based upon soft tissue thickness. The screw is advanced with a screwdriver, and the base component is fixed on the screw head. Depending upon imaging modality, the appropriate imaging marker is attached to the base component. In order to eliminate shift in marker position, care should be taken to completely seat the marker on the base component. At least 3 imaging markers are placed and will remain in position during scanning.

Angiography, CT, MRI, or PET image data can be transferred to navigation systems (e.g. Zeiss MKM System, Elektra Wand, Radionics OAS, etc.) for the surgical procedure. As with other neurosurgical procedures, the patient is first immobilized in a head rest such as a Mayfield to maintain constant patient position relative to the operating environment. For visual and wand registration systems, the imaging markers are removed and replaced with the optical (black-anodized alloy) markers to provide visual or tactile reference points identical to those provided by the imaging markers during scanning. Additionally, the optical markers have the option of being used with a stereotactic frame, requiring use of special adapters also provided with the system. The Marker System is typically implanted for 1-2 days, spanning imaging and treatment procedures, but can be left in place for up to 30 days for fractionated radiotherapy. Note that fractionated or intermittent procedures require re-registration of the Marker System using the same procedures and products previously indicated. The base components, marker balls, and optical markers are removable for fractionated radiotherapy, reducing the projection of the implant when the marker is not in use.

[2] Elof Eriksson, M.D., and Per-Ingvar Branemark, M.D., "Osseointegration from the Perspective of the Plastic Surgeon," *Plastic and Reconstructive Surgery*, March 1994, 93(3): 628-629, March 1994.

The Marker System is compatible with the following stereotactic products:

Howmedica Leibinger® ZD Stereotactic Frame
Howmedica Leibinger® STP Stereotactic Planning Software

5.0 Intended Use

Draft labeling can be found in Exhibit A.

5.1 Indications

- The Marker System is intended for establishing fixed reference points in patients requiring stereotactic surgery. Examples of situations necessitating stereotaxy could include patients in need of biopsy, resection, lesion generation, implantation of radioisotopes, and small field external beam radiotherapy.

- The Marker System can be used as an accessory with all currently marketed Howmedica Leibinger® stereotactic systems and can also be used with frameless navigation systems from other manufacturers.

5.2 Contraindications

Cranial markers should not be used in the following situations:

- Bone infection

- Skin infection

5.3 Precautions

- Imaging and optical markers must be completely seated into the base components or frame adapters in order to reproduce exact positioning after removal and replacement.

- When filling hollow imaging markers with contrast medium, air bubbles must be avoided to optimize imaging accuracy.

- Markers should be placed in calvarial bone of thickness greater than the threaded length of the selected implant to prevent risk of implant protrusion into the dura.

- Markers placed for MRI imaging should be located near the target site to facilitate re-registration.

- Hollow imaging markers containing contrast medium should be removed from the base components after scanning to reduce the potential for contrast medium to be spilled.

- Contact between the imaging marker balls and surgical cloth during scanning should be prevented to reduce the risk of fluid absorption.

6.0 Non-Clinical Study

Departments of Neurosurgery, Computerized Tomography, and Neurology
University of Innsbruck, Innsbruck, Austria

A study was conducted at the University of Innsbruck (Innsbruck, Austria) to evaluate the image registration accuracy of the Marker System in CT and MRI use. 35 markers were placed into holes of known position on three platforms of a phantom assembly. The central cylinder of the phantom was filled with diluted contrast agent, and the test assembly was placed into a standard CT head coil along with a control assembly. Gold-filled imaging markers were used for CT scans, while the contrast agent used for MRI imaging was not reported. The marker images present on the monitor after scanning were registered by manually placing a cursor in the center of each visible marker dot. Note that this testing did not involve the use of an automatic detection algorithm for determining image center; this tool, commonly incorporated into imaging software, improves registration accuracy. 16 combinations of 4 markers and 16 combinations of 3 markers were tested for accuracy. The following results were obtained:

	Mean Correlation Error	
	CT	MRI
3 markers	1.6 mm	2.2 mm
4 markers	1.2 mm	1.1 mm

Considerably higher accuracies--0.6 mm to 0.8 mm--were obtained with only three markers when these markers were all on the same platform of the phantom. This indicates that magnetic field distortion--independent of the marker system used--reduces accuracy as distance increases between the plane defined by the markers and the feature to be registered. The pooled mean, combining 3-marker and 4-marker results from both imaging methods, was

under 2 mm. This agrees with clinically accepted accuracy levels for stereotaxic procedures. See Exhibit C for additional information.

7.0 Clinical Study

Neurosurgery Department, Hopitaux des Armees, Paris, France

The Marker System was assessed in 15 patients undergoing surgery with the Zeiss MKM navigation system after CT or MRI imaging. Number of markers placed and imaging modality is shown in the following table:

# Markers	3	4	5
# Patients	1	13	1
Imaging Mode	CT	MR	CT+MR
# Patients	1	13	1

All screws were placed one day pre-operatively under local anesthesia. Placement sites were determined by the neurosurgeon based upon the pre-planned surgical access route. In each case, all screws were placed close to the access site with the exception of a control placed at a distance to improve referencing precision.

No problems were encountered with screw placement, tissue condition, or infection. CT or MRI image clarity was not impaired by artifacts. Optical referencing accuracies ranged from 0.6 mm to 1.5 mm--this compares very favorably with accuracies attainable with stereotactic frames.

8.0 Substantial Equivalence

Components of the Marker System are substantially equivalent to the ZD stereotactic frame incorporated in the STP Complete Module Set for stereotaxy [510(k) K892425] and to Wurzburg titanium bone screws [510(k) K854886]. Both devices are listed as predicates because the Marker System merges the long history of bone screw use in the craniofacial area with stereotaxy to provide a frameless marker system with accuracy equivalent to stereotactic frames. Specific comparisons are made in the following table:

Feature	Cranial Marker	ZD Stereotactic Frame (STP Complete Module Set)	Wurzburg Titanium Bone Screws
510(k) Number	n/a	K892425	K854886
Indication	establish a three-dimensional coordinate system for stereotactic surgery	establish a three-dimensional coordinate system for stereotactic surgery	bone fixation in craniofacial area
Stereotaxic Accuracy	0.6-2.2 mm (see sections 3.0 and 4.0)	1 mm	n/a
Marker Diameter	2.0 mm	1.6 mm for MRI 0.2 mm for CT	n/a
Material	titanium screws Udel marker balls contrast agent dependent upon imaging modality -CT, angiography: gold ball --MRI, PET: at discretion of physician	pins: titanium point, carbon fiber and plastic housing contrast agent dependent upon imaging modality --CT, angiography: stainless steel wire --MRI, PET: at discretion of physician	titanium
Screw Diameter	2.0 mm	n/a	2.0 mm
Threaded Length	4 or 5 mm	n/a	3.5-13.5 mm
Thread Pitch	1 mm	n/a	1 mm

9.0 Bibliography

Eriksson, Elof, M.D., and Branemark, Per-Ingvar, M.D. "Osseointegration for the perspective of the plastic surgeon." *Plastic and Reconstructive Surgery,* 93(3): 626-637, March 1994.

Levivier, Marc, M.D., et. al. "Diagnostic yield of stereotactic brain biopsy guided by positron emission tomography with [18F]fluorodeoxyglucose." *Journal of Neurosurgery,* 82(3): 445-452, March 1995.